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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,840	11/06/2000	John A. Drewe	1735.0410002/RWE/BEC	8076

7590 05/18/2004

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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/705,840

**Applicant(s)**

DREWE ET AL.

**Examiner**

Binta M. Robinson

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41, 42, 44-47, 50, 51, 53, 54, 60, 63, 64, 66-72, 75-78, 80 and 81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41, 42, 44-47, 50, 51, 53, 54, 60, 63, 64, 66-72, 75-78, 80 and 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### Detailed Action

Claims 41, 42, 44-46, 47, 50, 51, 53, 54, 60, 63-72, 75, 76, 77, 78, 80, 81 are pending.

The Group I elected invention, drawn to claims 41, 42, -46, 47, 50, 51, 53, 54, 60, 63-72, 75, 76, 77, 78, , 80, 81, which is drawn to the compound of formula I wherein Z is NR<sup>8</sup>R<sup>9</sup>, and R<sup>8</sup> and R<sup>9</sup> are independently H or C<sub>1</sub>-C<sub>4</sub> alkyl, Y is CN, A is phenyl or carbocyclic aryl, B is indolo, X is O, pharmaceutical composition containing said compound is modified such that will be examined below. The restriction requirement is revised to also restrict out claims 64-65 from examination since these claims are drawn to multiple active ingredients. The restriction is FINAL.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 42, 44, 45, 46, 47, 50, 51, 53, 54, 60, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 19, 20, 21-28, 81 of copending Application No. 2003/0065018. Although the conflicting claims are not identical, they are not patentably distinct from each other because in Application No. 2003/0065018, pharmaceutical compositions are

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claimed containing the instant indolo pyran compound species which anticipate the instant pharmaceutical composition comprising a compound of formula I drawn to the generic genus of formula I as well as instant pharmaceutical compositions comprising a specific compound species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 75, 76, 77, and 78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 75, 76, 77 and 78 of copending Application No. 2003/0065018. Although the conflicting claims are not identical, they are not patentably distinct from each other because in, Application No. 2003/0065018, indolo pyran compound species are claimed which anticipate the instant compounds of formula I drawn to the generic genus of formula I as well as the species claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

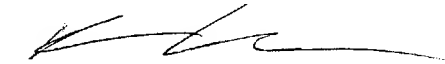
A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



BMR  
May 17, 2004



JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1200